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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,625	12/04/2003	Harry A. Dugger III	11122-039-999	5742

20582 7590 07/14/2004

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,625	DUGGER, HARRY A.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-29 and 41-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-29 and 41-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 19-25, 27-29, 41 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) in view of Purewal et al (5,605,674).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or buccal mucosa (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically active agent, a pharmaceutically acceptable solvent for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents such as fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49). The concentration of the solubilized active agent can range from 1 and 50% by weight (col. 8, lines 1-9). The acceptable carrier is intended to be any suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus

the active agent may be admixed with carriers such as spray-solution or any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include anti-opioid agents, anti-migraine agents, anesthetics, pain control agents, stimulants, neurotransmitter antagonists, etc (cols. 12-31).

Kanios lacks specific disclosure on the use of propellants in the spray formulation.

Purewal et al teaches medicinal aerosol formulations which comprise a medicament, a propellant such as 1,1,1,2-tetrafluoroethane and at least one compound having a higher polarity than the said propellant. Purewal, also discloses that aerosol formulations may contain a saturated hydrocarbon propellant, e.g., n-butane, isobutane, pentane and isopentanes (col. 1, lines 60-65). The formulation may also contain the hydrocarbons such as propane, butane isobutane, isopentane, etc, as its high polarity adjuvants (col. 2, lines 19-26).

Puerwal discloses that the aerosol formulations may e delivered to human lung via a metered dose inhaler (col. 2, lines 32-36 and col. 5, lines 1-3). The active agents suitable for the said aerosol formulations are listed in column 5, line 47 to column 6, line 19.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the spray formulations of Kanios by adding a

suitable propellant as taught by Purewal with the reasonable expectations of preparing a spray formulation containing propellants which assist in delivery of medicaments to the desired site and ultimately potentiates its absorption.

Claims 16-18, 26 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al and Purewal et al, as applied to claims 15, 19-25, 27-29, 41 and 48-55 above, and further in view of Singer et al (5,364,616).

The combined references, discussed above, lack disclosure on the concentration range and examples of the flavoring agents.

Singer teaches methods for prevention or treatment of gingivitis or periodontitis comprising topical administration to oral cavity, a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound, and oral care compositions used thereof. Compositions comprise about 0.001 to about 20% of a H-2 antagonist such as cimetidine, about 2 to about 99% of an oral carrier and about 0.04 to about 2% of flavoring agent by weight. The suitable carriers include ethanol, water and polyhydric alcohols such as glycerin, polyethylene glycol and propylene glycol. Suitable flavoring agents include menthol, oil of wintergreen, oil of peppermint, oil of clove, etc (col. 15-17).

Singer discloses that the said compositions, suitably in the form of a mouthspray, may optionally include other agents such as other active agents such as antibiotics, anti-inflammatories, vitamins and minerals (col. 18-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings on the spray formulations taught by the combined references, to look in the art for relative and suitable concentration range and examples of the flavoring agent with the reasonable expectations of preparing an oral formulation that is acceptable and tolerable by patients, since flavoring is an important aspect of oral formulations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-29 and 41-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/327,195. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims 15-29 and 41-55 are generic to all that is recited in claims of copending Application No. 10/327,195. That is, claims of copending

Application No. 10/327,195 fall entirely within the scope of claims 15-29 and 41-55. Specifically the formulations containing certain classes of active agents of the copending Application No. 10/327,195 fall within the scope of the formulations of claims 15-29 and 41-55. For example, pain control agents of the instant application fall entirely within the scope of the sleep inducers of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

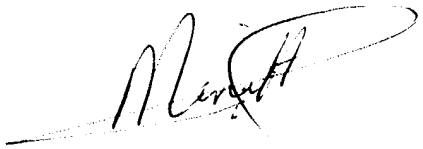
Claims 15-29 and 41-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/726,585. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims 15-29 and 41-55 are generic to all that is recited in claims of copending Application No. 10/726,585. That is, claims of copending Application No. 10/726,585 fall entirely within the scope of claims 15-29 and 41-55. Specifically the formulations containing certain classes of active agents of the copending Application No. 10/726,585 fall within the scope of the formulations of claims 15-29 and 41-55. For example, anti-migraine agents and anesthetics of the instant application fall entirely within the scope of the neurotransmitter antagonists of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
Examiner
Art Unit 1616
July 12, 2004